IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

JANICE NOWELL,

Plaintiff,

v. No. 2:17-cv-01010-JB-SMV

MEDTRONIC, INC., a Minnesota Corporation;
COVIDIEN PLC, an Irish Corporation;
COVIDIEN, LP, a Delaware Limited Partnership;
and MEDTRONIC PLC, an Irish Corporation,

Defendants.

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

Plaintiff's Opposition ("Opp.") confirms that the claims in her Second Amended Complaint ("SAC") are time-barred. Plaintiff's Opposition also fails to identify well-pleaded allegations that could support the necessary elements of any of her claims. For either reason, or both, Defendants' Motion to Dismiss ("MTD") should be granted.

I. Plaintiff's Claims Are Barred by the Statute of Limitations.

Dismissal under Rule 12(b)(6) is appropriate when the "uncontroverted facts" allege "dates that appear, in the first instance, to fall outside the statutory limitations period." *Anderson Living Tr. v. WPX Energy Prod., LLC*, Nos. CIV 12-0039 JB/SCY, 12-0040, 2015 WL 3543011, at *34 (D.N.M. May 26, 2015); *see also Watkins v. Craft*, 455 F. App'x 853, 854 (10th Cir. 2012). Here, the uncontroverted facts establish that each claim is barred by the applicable statutes of limitations.

A. Plaintiff Does Not Dispute that her Warranty Claims Are Untimely.

Plaintiff does not address Defendants' argument that her warranty claims are untimely, and thus concedes the point. *See* MTD at 7; *Pennington v. Northrop Grumman Space & Mission*

Systems Corp., 269 F. App'x 812, 820 (10th Cir. 2008) (declining to consider Plaintiff's argument where it was not raised in opposition to Defendant's motion for summary judgment).

Plaintiff's hernia mesh surgery occurred on October 27, 2010. The warranty claims carry a four-year statute of limitations period (N.M.S.A. § 55-2-725(1)), but Plaintiff did not file suit until October 5, 2017. Since the discovery rule does not apply to warranty claims, the warranty claims are untimely. *See Porcell v. Lincoln Wood Prods., Inc.,* No. CIV-08-0617 MCA/LFG, 2010 WL 1541264, at *4 (D.N.M. Mar. 31, 2010). They should be dismissed with prejudice.

B. Plaintiff's Negligence and Strict Liability Claims Are Also Untimely.

In New Mexico, negligence and strict liability claims carry a three-year statute of limitations periods. N.M.S.A. § 37-1-8. Again, although Plaintiff had her hernia mesh surgery on October 27, 2010, she did not file suit until almost seven years later on October 5, 2017. Plaintiff attempts to salvage her claims by contending that she "did not reasonably discover that the Parietex was causing her injuries until October 8, 2014." Opp. at 13. But Plaintiff acknowledges that she required a second surgery, on April 27, 2011, because Defendants' mesh allegedly "*began to pull away from the actual edges*." SAC. ¶ 38 (emphasis added).[1] At this point, more than six years before she filed her Complaint, Plaintiff acquired the "knowledge of facts, conditions, or circumstances" to cause a "reasonable person to make an inquiry" as to

[1] In her Opposition, Plaintiff now alleges that her physician "affirmatively told her that there was not a problem with the mesh" and specifically advised her that the mesh "was not causing her symptoms." Opp. at 14. That is not what she alleged in her Complaint. There, she alleged only that following her April 27, 2011 surgery, she was "**not informed** by the doctor that there was any problem with the mesh itself", SAC. ¶38, and that "[b]etween April 27, 2011 and March 1, 2014," she was "**not advised** that [her symptoms] were caused by the mesh." SAC. ¶38. Further, Plaintiff's new claims about her physician's statements, if true, raise serious questions about her ability to establish causation.

whether the mesh product was responsible for her injuries. *See Butler v. Deutsche Morgan Grenfell, Inc.*, 140 P.3d 532, 541 (N.M. Ct. App. 2006); *see* MTD at 9–10.

Plaintiff's duty to inquire only intensified as, "[b]etween April 27, 2011 and March 1, 2014, [Plaintiff] began experiencing symptoms including but not limited to exhaustion and pain *in the area of the mesh*." SAC. ¶ 38 (emphasis added). There is no allegation in her SAC as to why she did not make reasonable inquiry at the time of her April 27, 2011 surgery as to whether the mesh was (allegedly) sufficiently defective to bring suit, much less as to why she did not make an inquiry in the three years between the date of her surgery and after her CT scan in March 2014, as to the cause of the "pain in the area of the mesh." Fundamentally, Plaintiff's SAC is devoid of any allegations "that if she had diligently investigated the problem she would have been unable to discover the cause of her injury." *Martinez v. Showa Denko, K.K.*, 964 P.2d 176, 181 (N.M. Ct. App. 1998). Because she does not allege facts to toll her claims, Plaintiff's negligence and strict liability claims are time-barred.

To be sure, Ms. Nowell attached three exhibits to her Opposition (but not her SAC), in an attempt to shore up the deficiencies in her Complaint. But it is plainly improper for a plaintiff – especially one who has already had the opportunity to file an initial complaint and two amended pleadings – to raise fact issues never mentioned in her complaints in an attempt to save her case from dismissal in a brief opposing a Rule 12(b)(6) motion. Such practices show a lack of respect for the pleadings requirements of the federal rules. In any event, the first two exhibits, a CT scan and clinical notes from the scan are irrelevant, as they relate to the revision surgery she had in 2014 - *after* the statute of limitations period had already expired. Thus, even if the Court could consider these documents on a motion to dismiss, *but see Great American Ins. Co. v. Crabtree,* No. CIV 11-1129 JB/KBM, 2012 WL 3656500 (D.N.M. Aug. 23, 2012) at *21 (citing *Casanova v. Ulibarri*, 595 F. 3d 1120, 1125 (10th Cir. 2010); *Gossett v. Barnhart*, 139 F. App'x 24 (10th

Cir. 2005)), they do nothing to address the fact that she was on discovery notice prior to the expiration of the statute of limitations in October 2013.

Ms. Nowell also submits an affidavit in which she claims that she inquired of her treating physician as to the cause of the pain around her mesh and was told by him that it did not relate to the mesh itself. Again, this is clearly improper because the Court cannot consider it on a motion to dismiss. *See Anderson* at 13 (refusing to consider Plaintiffs' affidavits because "to the extent that the Court can ascertain what the documents even are – they are not documents to which the [Complaint] refers, and were, in fact, produced … after the filing of the [Complaint]."). "There is no indication that the affidavit is considered a part of [Plaintiff's] allegations in the [Complaint]. If [Plaintiff] wanted the Court to consider these allegations as part of [her Complaint], [she] should have pled them in [her] pleading, and not ask the Court to consider an outside document on a motion to dismiss." *Lymon v. Aramark Corp*., 728 F. Supp. 2d 1222, 1261 (D.N.M. 2010).

Even if considered, the affidavit also does not save her time-barred claims. In her Opposition, Ms. Nowell claims that before October 8, 2014, she was told by her physician that the mesh was not the cause of her injuries. Either this diagnosis was true, which is fatal to Ms. Nowell's case, or it was a misdiagnosis. However, "a misdiagnosis does not relieve a patient of all responsibility in pursuing the cause of her symptoms, and continued reliance on a misdiagnosis in the face of contrary evidence may be unreasonable." *Robinson v. BNSF Ry. Co.,* No. 11–2464–JWL, 2012 WL 4747155 (D. Kan. Oct. 4, 2012) (quoting *Mest v. Cabot Corp.,* 449 F.3d 502 (3rd Cir. 2006)).[2] Plaintiff here affirmatively alleges that she had to have surgery to repair the mesh within a year of it being implanted. Plaintiff also affirmatively alleges that she

[2] The District Court's decision was affirmed by the 10th Circuit on appeal. *See Robinson v. BNSF Ry. Co.,* 533 F. App'x 792 (10th Cir. 2014).

continued to have pain in the area of her mesh for *three more years*. Plaintiff cannot rely on her physician's alleged misdiagnosis to toll her claims when she continued to experience pain occurring in the area of the mesh. Because it was unreasonable for her not to have undertaken further inquiry, Plaintiff's strict liability and negligence claims remain time-barred.

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In the alternative, Plaintiff argues that the Court should exercise its discretion to accept these Exhibits and "treat the Defendants' motion to dismiss as a motion for summary judgment pursuant to Fed. R. Civ. P. 12(d)." Opp. at 2; 15. Plaintiff's request should be denied as moot. As discussed above, even if considered, they do not save her claims.

In any event, Rule 12(d) permits such a conversion only if "all parties [are] given reasonable opportunity to present all material made pertinent to such a motion by Rule 56." Fed. R. Civ. P. 12(d). Here, Plaintiff, who has filed three different versions of her Complaint already, has had repeated opportunities to include all necessary and relevant information in her SAC. On the other hand, Defendants have had no opportunity to discover, much less present, material pertinent to a Rule 56 motion. As this Court observed in *Anderson*, Defendants, as the moving parties, are entitled to be the "masters of their own motion." *Id.* at 13. Because Plaintiff has been given three opportunities to plead her claims, Defendants have proceeded to move under Rule 12(b)(6). Because Defendants have had no opportunity to take discovery on Plaintiff's exhibits in connection with a proposed Rule 56 motion on statute of limitations, Plaintiff's request for a Rule 12(d) conversion should be denied. If the Court is inclined to convert the motion into one for summary judgment, Defendants would respectfully request the opportunity for the parties to take discovery *limited to the statute of limitations issue*, before the Court considers the motion.

II. Plaintiff Fails to State a Claim for Negligence.

Plaintiff's Opposition also fails to point to any well-pleaded facts in the SAC alleging any breach of duty on the part of Defendants that caused Plaintiff's injuries.[3] In relation to "a negligence claim for a defective product," Plaintiff cites her SAC to argue that she "established the existence of a duty owed," a "breach of that duty," and "a causal connection between the Defendants' conduct and her injuries." Opp. at 5–6 (quoting *Parker v. E.I. DuPont de Nemours & Co., Inc.,* 909 P.2d 1, 11 (N.M. Ct. App. 1995)).[4] She further argues that "manufacturers and distributors of products have a duty to use ordinary care in producing products so as to avoid a foreseeable risk of injury caused by a condition of the product or the manner in which it is used." Opp. at 6 (quoting *Bryco Arms* at 645). Plaintiff alleges that the "unreasonable inspection" of the product, "improper testing" of the product, and "unreasonable packaging" of the product all demonstrate a "lack of ordinary care used by the Defendants in their design of the product." Opp. at 6–7.

None of these pleadings reference any *specific* acts or omissions on the part of Defendants suggesting that they breached their duty of care to Plaintiff. The SAC merely provides generalized allegations that the product was not properly inspected, tested, or packaged, without specifying *how* the inspections, testing, or packaging failed to satisfy a manufacturer's duty to exercise ordinary care. *See Mims v. Davol, Inc.,* No. 2:16-cv-00136-MCA-GBW, 2017

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[3] Plaintiff relies on two inapposite cases in support of her arguments in relation to the pleading standards. Opp. at 3. Both *Breidenbach v. Bolish*, 126 F.3d 1288 (10th Cir. 1997) and *Currier v. Doran,* 242 F.3d 905 (10th Cir. 2001) discuss pleading requirements ***only*** in the context of a defendant raising a qualified immunity defense, which obviously has no bearing in this case.

[4] Plaintiff relies on *Parker*; *Smith ex rel. Smith v. Bryco Arms,* 33 P.3d 638, (N.M. Ct. App. 2001); *Fernandez v. Ford Motor Co.,* 879 P.2d 101 (N.M. Ct. App. 1994); *Garner v. Raven Indus., Inc.*, 732 F. 2d 112 (10th Cir. 1984) for her negligence and strict liability claims. Opp. at 5–7. None of these cases involved a review of a motion to dismiss and, as such, none addressed the adequacy of the plaintiff's pleadings.

WL 3405559, at *4 (D.N.M. Mar. 22, 2017) (dismissing Plaintiff's negligence claim as it pertained to a manufacturing defect); *see* MTD at 11. The absence of clear allegations as to *how* Defendants breached their duty is especially problematic because, unlike other mesh products, none of the Defendants' mesh products (including Parietex Composite Mesh) has been subject to recall or other adverse regulatory action. *See* MTD at 5.[5] Absent such pleadings, Plaintiff fails to fulfill her burden of proving a breach of duty.

Plaintiff also fails to plead a causal connection between Defendants' conduct and her injuries. In her Opposition, Plaintiff claims that she has "articulated theories of causation that are based on scientific research," referring to the three scientific articles cited in her SAC. Opp. at 11. None of these articles allege or even suggest that Parietex Composite Mesh caused Plaintiff's alleged injuries. Each article focuses on the underlying risks common to *all* hernia repair surgeries (not just surgeries involving Defendants' mesh), risks that are well-known in the medical community. The first article, "Central Failures of Monofilament Polyester Mesh Causing Hernia Recurrence: A Cautionary Note," examines "Parietex TCM" mesh (which is <u>not</u> the product at issue) and discusses the issue of mesh failure due to tearing—an issue Plaintiff does not allege and which is not causally connected to Plaintiff's alleged injury: infection. SAC. ¶ 38. The second article, "Postoperative Mesh Infection—Still a Concern in Laparoscopic Era," summarizes published findings and mentions Defendants' Parietex mesh only once; it says nothing about Parietex Composite mesh, the product at issue here. While the third article, "Novel in Vitro Model for Assessing Susceptibility of Synthetic Hernia Repair Meshes to Staphylococcus aureus Infection," discusses "Parietex Composite" mesh in assessing the

[5] As noted in Defendants' motion to dismiss at 13, the Southern and Western Districts of New York have recently dismissed on *Twombly/Iqbal* grounds similar complaints involving Defendants' hernia mesh products. *See Rincon v. Covidien,* No. 16-CV-100333, 2017 WL 2242969 (S.D.N.Y. May 22, 2017), and *Black v. Covidien,* No. 17-CV-6085FPG, 2018 WL 573569 (W.D.N.Y. Jan 26, 2018).

wettability of the mesh only – it does not suggest a potential defect in Defendants' mesh that could be causally linked to Plaintiff's injuries. *See* MTD at 15. Without sufficient pleadings as to causation, Plaintiff's negligence claim warrants dismissal.

III. Plaintiff Fails to State a Claim for Strict Liability – Design Defect and Failure to Warn.

Plaintiff asserts that any overlap between her negligence and strict liability claims arises from the "similarity of elements between the two causes of action." Opp. at 10. Plaintiff misses the point. Defendants argue that ***because*** pleading negligence requires more than pleading strict liability and ***because*** Plaintiff has failed to plead strict liability adequately, then it follows that her negligence claims also warrant dismissal. *See* MTD at 11.

Plaintiff alleges strict liability claims in relation to design defect and failure to warn. Both require pleading that "the product was defective" and "unreasonably dangerous." *See* MTD at 12. First, Plaintiff has not pleaded a specific design feature that rendered Defendants' mesh defective. Instead, her SAC relies on a generalized list of alleged flaws that include: the mesh's material caused an "immune reaction"; the mesh was designed "to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh"; "[b]iomechanical issues . . . including, but not limited to, the propensity of the Product to disintegrate"; and the mesh's "inelasticity." SAC. ¶ 121; *see* MTD at 13. Furthermore, Plaintiff never alleges a feasible alternative design existed that lacked the alleged design defect and would have prevented her injuries. *See Morales v. E.D. Etnyre & Co.,* 382 F. Supp. 2d 1278, 1283 (D.N.M. 2005) ("Thus, to the extent that a plaintiff could come to court and merely criticize a product, the Court believes that the New Mexico law required the plaintiff to propose an alternative design.").

In her Opposition, Plaintiff claims that a feasible alternative design would be one "made from a material that a) was biologically compatible; and b) was not susceptible to mechanical

failure." Opp. at 11. Even assuming, *arguendo*, that this allegation was contained in her SAC the question remains: what is the design that (supposedly) is compatible with Plaintiff's specific biology, and not susceptible to mechanical failure? As pleaded, there is no indication that such a design is feasible, let alone that it would "make the product safer." *Reed v. Pfizer, Inc.,* 839 F. Supp. 2d 571, 578 (E.D.N.Y. 2012); *see* MTD at 14–15.[6] Furthermore, Plaintiff's Complaint fails to allege concretely, as is required to state a claim for design defect, "that a differently-designed … device (one [made from a different material]) could have been used during Plaintiff's surgery and would have prevented her injuries." *Simon v. Smith & Nephew, Inc.,* 990 F. Supp. 2d 395 (S.D.N.Y. Dec. 3, 2013); *see Bertini v. Smith & Nephew, Inc.,* No. 13 CV 0079 (BMC), slip op., 2013 WL 6332684 (E.D.N.Y. July 15, 2013) (rejecting claim of feasible alternative design because "[t]here is no way to tell whether other R3 liners would have been appropriate for implantation in plaintiff."). Because Plaintiff is unable to plead the existence of a specific design defect and feasible alternative design, her claim must be dismissed with prejudice.

Second, Plaintiff has not pleaded facts suggesting the elements of her failure to warn claim. Plaintiff claims that Defendants "failed to provide sufficient warnings" to put her "on notice of the dangers and adverse effects caused by implantation of the Product." Opp. at 9. She argues that Defendants marked the product as "safe" and as "free from the kinds of risks and hazards that the [Product] actually posed." Opp. at 9 (quoting Compl. ¶9).

Plaintiff's allegation that "Defendants did not adequately warn … of the dangers of the Product" does not actually "disclose the nature and extent of the danger" that she claims not to

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[6] Plaintiff offers "polypropylene" as an example of preferred "hydrophobic material" in her Complaint. SAC. ¶ 28. However, Davol's Composix Kugel Mesh and Ethicon's Physiomesh Flexible Composite Mesh are both made from polypropylene and, unlike Defendants' products, have both been subject to recalls. *See* MTD at 4.

have been warned against. *Jones v. Minn. Mining & Mfg. Co.,* 669 P.2d 744, 750 (N.M. Ct. App. 1983). *See* MTD at 17. Furthermore, Plaintiff has pleaded no facts indicating that if Defendants had provided these proper warnings, her physician's treatment decision would have altered. This is especially so, given that Plaintiff's primary injury, infection, is a known risk associated with hernia repair surgery generally. *See Silva v. Smithkline Beecham Corp.,* No. 31, 276, 2013 WL 4516160, at *3 ("Plaintiffs must show that adequate warnings would have altered Dr. Lopez- Colberg's decision to treat Patient with Paxil or its generic equivalent."). Because Plaintiff "do[es] not identify what warnings Defendants gave to [her] physician, how they were inadequate, or what warnings should have been given, her failure to warn claim must be dismissed." *See Black* at 4.[7]

IV. Plaintiff Concedes the Insufficiency of Her Manufacturing Defect and Warranty Claims.

Plaintiff concedes that "despite due diligence she has been unable to obtain information pertaining to the exact manufacturing process and specific warranty language." Opp. at 9. As such, she is unable to plead her claims to the standard imposed by *Twombly/Iqbal.*

Nevertheless, Plaintiff claims that the information necessary to plead her claims is "within the exclusive control of the Defendants" and "will be developed after discovery is complete and an expert witness evaluates the information."[8] Opp. at 13; 4. She argues that

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[7] Instead of pleading all the elements of a strict liability claim, Plaintiff chooses to focus solely on how Defendants' mesh allegedly caused her injuries. Opp. at 8. She argues that that she has pleaded causation because her physician "removed an infected and disintegrated Parietex mesh in her abdomen." *Id.* As with her negligence claims, Plaintiff asks the Court to infer a strict liability claim from the fact that she allegedly suffered injuries. *See* MTD at 11 (quoting *Pac. Indem. Co. v. Therm-O-Disc, Inc.,* 476 F. Supp. 2d 1216 (D.N.M. 2006)).

[8] Plaintiff cites *Daubert v. Merrell Dow Pharms. Inc.,* 509 U.S. 579, 588 (1993) to argue that she is "entitled to retain an expert witness for the purpose of developing such scientific arguments" should this motion be denied. Opp. at 4. This is obviously true. However, when considering the adequacy

should the motion be denied, she would "have the opportunity to develop and further substantiate the claims for which she has reasonably plead." Opp. at 5.

A plaintiff cannot successfully plead a claim for manufacturing and warranty claims based on vague allegations and the hope that discovery eventually will reveal some basis for the claim. Plaintiff herself relies on *DM Research v. College of Am. Pathologists*, 170 F.3d 53, 56 (1st Cir. 1999), which states that "conclusory allegations in a complaint, if they stand alone, are a danger sign that the plaintiff is engaged in a fishing expedition." (affirming District Court's dismissal of a manufacturer's claims because of the lack of allegations as to a conspiracy claim.). Regardless of what discovery would show in relation to her warranty, manufacturing defect and other claims generally, Plaintiff has not met her threshold burden to plead sufficient facts to satisfy the *Twombly/Iqbal* standard. As such, her claims must be dismissed with prejudice.

V. Plaintiff is not Entitled to Punitive Damages.

In her Opposition, Plaintiff states that "punitive damages do[] not constitute an independent claim; rather, it is 'part and parcel of a liability of determination.'" Opp. at 11 (quoting *Mason v. Texaco, Inc.,* 948 F.2d 1546, 1554 (10th Cir. 1991)). Therefore, Plaintiff alleges, "punitive damages is not an allegation that can be dismissed for failure to state a claim upon which can be granted." Opp. at 11 (citations omitted).

Plaintiff misses the point. Plaintiff's request for punitive damages ***requires*** an allegation that the Defendants engaged in conduct that was "'maliciously intentional, fraudulent, oppressive, or committed recklessly or with a wanton disregard to the plaintiffs' rights.'" *Perfetti v. McGahn Med.*, 662 P.2d 646, 654 (N.M. Ct. App. 1983) (quoting *Loucks v. Albuquerque Nat'l Bank,* 418 P.2d 191, 199 (N.M. 1966)). Plaintiff has not pleaded any facts

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of her pleadings, Plaintiff is obliged to plead facts giving rise to cognizable legal claim – which she has not.

giving rise to such allegation and, therefore, on the face of her Complaint, punitive damages should not arise.

CONCLUSION

For the reasons stated above, Defendants respectfully request that the Court grant their motion to dismiss and dismiss Plaintiff's Complaint in its entirety, with prejudice.

Respectfully submitted,

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WE HEREBY CERTIFY that on the 4th day of May, 2018, we filed the foregoing electronically through the CM/ECF system, which caused all parties or counsel of record to be served by electronic means, as more fully reflected on the Notice of Electronic Filing.

MODRALL, SPERLING, ROEHL, HARRIS & SISK, P.A.

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